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(11) EP 0 853 923 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:  
22.07.1998 Bulletin 1998/30

(51) Int. Cl.<sup>6</sup>: A61B 17/74, A61B 17/17

(21) Application number: 97122921.6

(22) Date of filing: 28.12.1997

(84) Designated Contracting States:  
AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC  
NL PT SE  
Designated Extension States:  
AL LT LV MK RO SI

(30) Priority: 21.01.1997 IT VR970003

(71) Applicant: ORTHOFIX S.r.l.  
37012 Bussolengo (VR) (IT)

(72) Inventors:  
• Faccioli, Giovanni  
46040 Monzambano, Mantova (IT)

• Venturini, Daniele  
37065 Povegliano Veronese, Verona (IT)  
• Lavini, Franco  
37121 Verona (IT)  
• Renzi, Brivio Lodovico  
37131 Verona (IT)  
• Ten Veldhuys, Sander  
37138 Verona (IT)

(74) Representative:  
O'Byrne, Daniel Joseph  
c/o Fenzi & Associati,  
25, Via Savai  
37124 Verona (IT)

(54) Intramedullary cavity nail for the treatment of fractures of the hip

(57) An intramedullary cavity nail for the treatment of proximal femoral fractures, comprising a solid elongated body having a proximal portion (2) with at least one hole for accommodating corresponding screws (9,10) for stabilising the femoral neck, joined to a distal portion (3) with at least one distal hole (16) for accommodating at least one diaphysis screw for stabilising the distal part of the femur. The proximal portion (2) has a substantially constant diameter ( $\varnothing_p$ ) adapted to be stably anchored in a relatively limited length bore of the femur for reducing blood losses, while said distal portion (3) has a substantially constant diameter ( $\varnothing_d$ ) which is less than that of said proximal portion for being easily inserted in the medullary canal of the femur without any drilling. The proximal and distal portions (2; 3) are substantially rectilinear and form between themselves a predetermined deviation angle ( $\beta$ ) in a lateral plane. The proximal portion (2) has a pair of inclined holes (7, 8) adapted for accommodating respective cephalic screws (9, 10) for the fixing of the femoral head.

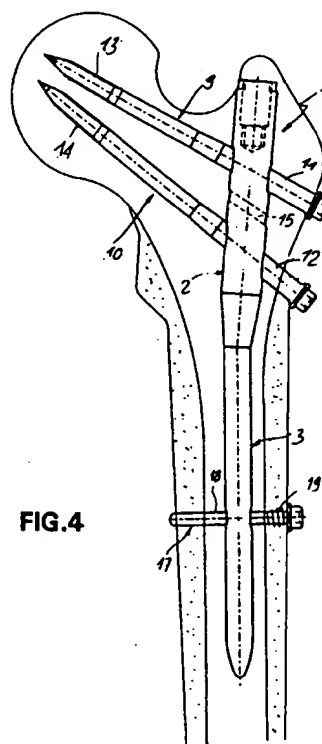


FIG. 4

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## Description

### Technical Field

The present invention relates to an intramedullary cavity nail for the treatment of proximal femoral fractures of the type comprising a solid elongated body having a proximal portion with at least one hole for accommodating corresponding screws for stabilisation of the femoral neck, united to a distal portion with at least one distal hole for accommodating at least one diaphysis screw for stabilisation of the distal part of the femur.

The invention also concerns an instrument for the installation of the nail in the medullary canal of the femur.

### Background Art

It is known that pertrochanteric fractures are the most frequent in connection with those of the region of the neck of the bone amongst geriatric patients. In fact, the advanced age and the pathologies which are encountered in these patients make necessary a timely stabilisation of skeletal injuries in order to reduce to a minimum the bed confinement and the rehabilitation times by means of interventions which are less sanguinary and invasive as possible. In fact, it is necessary to avoid the complications brought about by immobilisation syndrome which may be lethal for patients in delicate metabolic compensation and it is necessary to reduce blood losses related to the intervention to a minimum.

At the same time, the syntheses means utilised must be stable in order to allow the patient to very timely assume the seated position and already after two or three days after the intervention to reassume the erect stature with progressive weight.

A known technique for the consolidation of intertrochanteric, pertrochanteric, and subtrochanteric fractures of the femur involves the use of tubular intramedullary cavity nails with a proximal portion bent by some degrees in a medium-lateral plane with respect to the smaller diameter diaphysis portion in order to adapt to the physiological curvature of the femur. Sometimes, the curvature is present in two mutually orthogonal planes in order to favour further the adaptation of the medullary cavity of the bone.

The known tubular nails are generally fixed by means of two diaphysis nails in order to block the rotation of the nail and one or two cephalic screws for compressing the spongy tissue in the focus fracture.

A first drawback of the known intramedullary cavity nails of the above described type is constituted by the fact that they have both a proximal part and a distal part of relatively elevated diameter, generally greater than 10mm, and therefore their installation requires complex drilling of the bone for the entire length of the nail and can provoke internal stresses of the bone.

Moreover, the diaphysis screws are rather close to

the distal end of the nail and can provoke stress concentrations and rupture of the femur at the base of the nail.

Finally, the cephalic screws are normally mutually parallel and therefore the head can be subject to slipping with consequent losses of stability of the fracture.

### Disclosure of the Invention

A principal aim of the present invention is to eliminate or at least reduce the above described drawbacks by providing an intramedullary cavity nail which has characteristics of elevated robustness, reliability and biocompatibility, and which is hardly invasive.

A particular aim is to provide an intramedullary cavity nail which requires minimum bone drilling operations and skin incisions so as to limit blood loss and operating intervention and rehabilitation times.

A further aim is to provide an intramedullary cavity nail of elevated biocompatibility and of reduced cost.

Another further aim is to provide an intramedullary cavity nail which is easily installable in the medullary canal with an extremely simplified and effective instrument.

In accordance with one preferred aspect of the invention, there is provided an intramedullary cavity nail of the type defined above, characterised by the fact that said proximal portion has a substantially constant diameter adapted to be stably anchored in a relatively limited length bore of the femur for reducing blood loss, while said distal portion has a substantially constant diameter smaller than that of said proximal portion for being easily inserted in the medullary canal of the femur without any drilling.

### Brief Description of Drawings

The particular characteristics and advantages of the invention will become apparent from the description of some preferred but not exclusive embodiments of the intramedullary cavity nail according to the invention, illustrated for illustrative and non-limiting purposes with the help of the attached drawing sheets in which:

Fig. 1 illustrates a lateral elevation view of the intramedullary cavity nail according to a preferred aspect of the invention;

Fig. 2 illustrates a detail of the nail of Fig. 1 seen according to arrow II;

Fig. 3 illustrates the detail of Fig. 2 seen according to arrow III;

Fig. 4 illustrates a lateral elevation view of the intramedullary cavity nail of Fig. 1 inserted in the medullary canal of a femur;

Fig. 5 illustrates a lateral elevation view of a detail of the nail of Fig. 4;

Fig. 6 illustrates a lateral elevation view of another detail of the nail of Fig. 4;

Fig. 7 illustrates a lateral elevation view of a part of

an instrument according to a preferred aspect of the invention for fixing the intramedullary cavity nail to the bone;

Fig. 8 illustrates a general lateral elevation view of the intramedullary cavity nail of Fig. 1, coupled to the instrument for insertion in the medullary canal.

#### Best Modes for Carrying Out the Invention

With reference to the cited figures, an intramedullary cavity nail according to a preferred aspect of the invention, indicated globally by the reference numeral 1, is generally constituted by a solid elongated body in biocompatible metal, for example titanium or stainless steel of the type AISI 316LVM, essentially formed by a proximal portion 2 united to a distal portion 3 by means of a substantially truncated-conical intermediate portion 4.

Both the portions 2, 3 are substantially rectilinear and their axes form between them a deviation angle  $\beta$  of limited value, for example included between  $4^\circ$  and  $5^\circ$ .

The proximal portion 2, having a length  $L_p$  included for example between 70mm and 80mm, has a substantially constant and relatively high average diameter  $\varnothing_p$ , for example comprised between 12mm and 16 mm and preferably equal to about 14mm, such as to be able to be stably anchored in a hole bored in the trochanteric zone of limited length of the bone. In this manner, one obtains a reduction of blood loss during the operation of tissue incision and a simplification of the surgical intervention with greater chances of success.

Towards the free end of the proximal portion 2, a threaded seat 5 is formed whose end edge has a diametrical notch 6.

In the proximal portion 2 there is provided at least one pair of transverse through holes 7, 8 for cephalic screws 9, 10 for stabilising the femoral head and inclined with respect to the axis  $a_p$  of the proximal portion 2.

The holes 7, 8 are inclined with respect to the axis of the proximal portion 2 by an average angle of about  $115^\circ$  and may be mutually inclined by about  $10^\circ$  so as to be convergent, in order to prevent the shifting of the head and the exit of the screws therefrom.

Preferably, the cephalic screws 9, 10 have respective proximal end portions 11, 12 with possibly but not necessarily increased diameter, stably engageable in the holes 7, 8 of the nail 2, and distal end portions 13, 14 with lesser or equal diameter, and with self-threading tips for screwing into the femoral head.

If necessary, in the proximal portion 2 there may be provided a third through hole 15, inclined by an average angle of for example about  $115^\circ$  with respect to the axis  $a_p$  for a medial Kirschner wire substantially coaxial to the femoral head, with a smaller diameter than the first two screws and not illustrated in the drawings.

The distal portion 3, having a length  $L_d$  included for example between 100mm and 120mm, has an average diameter  $\varnothing_d$  less than diameter  $\varnothing_p$  of the proximal por-

tion, for example included between 8mm and 10mm and preferably equal to about 9mm, so as to be able to be easily inserted in the medullary canal of the femur without any boring of the same.

In the distal portion 3 a single through hole 16 is provided, substantially perpendicular to the axis  $a_d$ , for a diaphysis stabilisation and torsional blockage pin 17. The hole 16 is preferably provided at about half of the length  $L_d$  so as to result sufficiently distant from the free tip of the pin and reduce risks of breakage of its end portion.

Preferably, the diaphysis pin 17 has a smooth portion 18 with a substantially constant diameter stably engageable in the hole 15, and a threaded proximal end portion 19 engageable in the spongy tissue of the bone.

Thanks to this configuration, the nail 1 allows for an optimal stabilisation and a stable and quick synthesis of the bone with a hardly invasive technique and with limited blood loss.

Both the cephalic screws and the diaphysis pin may be provided with the same materials as the nail for obvious reasons of biocompatibility.

According to a further aspect of the invention, there is provided an instrument for positioning the above described intramedullary cavity nail and for performing the necessary drilling of the bone.

Advantageously, such instrument is constituted by a drilling mask 20 which extends in a principal plane and is formed by a grip 21 which is graspable by the surgeon and from which a transverse appendix 22 having an end hole 23 extends. A guide sleeve 24 is keyed in the hole 23 having diametrical protrusions or end teeth 25 at its lower end which pass through the principal plane of development of the mask and which are engageable in the diametrical notch 6 of the seat 5 of the nail 1 in order to guarantee its alignment during the intervention.

A pin 26 with a manoeuvre knob 27 may cross the internal cavity of the sleeve 24 and has a threaded end 28 which engages in the threaded seat 5 of the pin 1 in order to guarantee its connection with the mask 20.

In the lower part of the grip 21 of the mask 20 there are provided guide holes for bone drilling bits in correspondence with the holes 7, 8, 15 and 16 of the nail.

In use, the surgeon performs the drilling of the trochanteric zone of the femur for about 10cm, whereafter the nail is inserted taking care that the notch 6 along the edge of its threaded seat is positioned in a lateral plane of the limb. Thereafter the nail is connected to the drilling mask 20 taking care that the protrusions or teeth 25 of the guide sleeve 24 of the later are engaged in the notch 6. Finally, the pin 26 is inserted in the sleeve 24 and its threaded end 28 is screwed in the threaded seat 5 of the pin thereby providing its stable connection. At this point, the drilling of the bone may be initiated in correspondence with the holes 7, 8, 15, 16 of the pin and finally the screws 9, 10, 17 may be inserted in the respective holes for providing the stabilisation of the femur in a rapid and secure manner.

For the insertion and stabilisation of such screws while avoiding accidentally dropping them, it is possible to utilise a particular T-shaped tool, illustrated clearly in Fig. 7 and globally indicated by the reference numeral 29. The tool has a manoeuvring stem 30 with a head 31 having a central locking appendix 32 of hexagonal section engageable in the hexagonal fitting of the screw and an external tubular portion 33 with a diametrical longitudinal notch 34 for forming two semicylindrical elastic wings which grip the head of the screw.

#### Claims

1. Intramedullary cavity nail for the treatment of femoral fractures, comprising a solid elongated body having a proximal portion (2) with at least one hole for accommodating corresponding screws (9, 10) for stabilising the femoral neck, joined to a distal portion (3) with at least one distal hole (16) for accommodating at least one diaphysis screw for stabilising the distal part of the femur, characterised by the fact that said proximal portion (2) has a substantially constant diameter ( $\varnothing_p$ ) adapted to be stably anchored in a relatively limited length bore of the femur for reducing blood losses, while said distal portion (3) has a substantially constant diameter ( $\varnothing_d$ ) which is less than that of said proximal portion for being easily inserted in the medullary canal of the femur without any drilling.
2. Intramedullary cavity nail according to claim 1, characterised by the fact that said proximal and distal portions (2; 3) are substantially rectilinear and form between themselves a predetermined deviation angle ( $\beta$ ) in a lateral plane.
3. Intramedullary cavity nail according to claim 2, characterised by the fact that said angle of deviation ( $\beta$ ) is comprised between  $3^\circ$  and  $10^\circ$  and is preferably equal to about  $5^\circ$ .
4. Intramedullary cavity nail according to claim 1, characterised by the fact that the diameter ( $\varnothing_p$ ) of said proximal portion (2) is comprised between 12mm and 16mm and is preferably equal to about 14mm.
5. Intramedullary cavity nail according to claim 1, characterised by the fact that the diameter ( $\varnothing_d$ ) of said distal portion (3) is comprised between 7mm and 11mm and is preferably equal to about 9mm.
6. Intramedullary cavity nail according to claim 1, characterised by the fact that said proximal portion (2) has a pair of inclined holes (7, 8) adapted for accommodating respective cephalic screws (9, 10) for the fixing of the femoral head.

7. Intramedullary cavity nail according to claim 6, characterised by the fact that said cephalic screws (9, 10) have a notably smaller diameter than that of said proximal portion (2) and are slightly convergent with respect to one another and with respect to the median axis of the femoral head in order to exert on the latter a reaction force with a longitudinal component for contrasting its shifting and/or the axial penetration.
8. Intramedullary cavity nail according to claim 7, characterised by the fact that said cephalic screws (9, 10) have respective maximum diameter portions (11, 12) for the accommodation in corresponding holes (7, 8) of said proximal portion (2), with a maximum diameter comprised between 3mm and 8mm and preferably approximately 7mm.
9. Intramedullary cavity nail according to claim 1, characterised by the fact of providing a single diaphysis screw (17) for contrasting torsional stresses of the nail, accommodated in a single hole (16) substantially perpendicular to the axis ( $a_d$ ) of the distal portion (3) provided towards the end of the latter farther from said proximal portion (2).
10. Intramedullary cavity nail according to claim 9, characterised by the fact that said diaphysis screw (17) has a substantially constant diameter principal portion (18) corresponding to that of said single hole (16) of said distal portion, and an increased diameter threaded portion (19).
11. Intramedullary cavity nail according to claim 10, characterised by the fact that said diaphysis screw (17) is positioned approximately at half length ( $L_d$ ) of said distal portion for avoiding breakage of the nail towards its free end.
12. Intramedullary cavity nail according to claim 1, characterised by the fact that said proximal portion (2) has, in correspondence with its free end, a threaded seat (5) for a connection pin (26) for connection to a drilling mask (20) arranged in the principal plane of the nail.
13. Intramedullary cavity nail according to claim 12, characterised by the fact that the edge of said threaded seat (5) has a diametrical notch (6) coplanar with the principal plane of the nail for the insertion of alignment protrusions (25) between nail and mask (20).
14. Intramedullary cavity nail according to claim 12, characterised by the fact that said drilling mask (20) has a grip (21) with a transversal appendix (22) having at its free end an axial hole (23) for the passage of said connection pin (26).

15. Intramedullary cavity nail according to claim 14, characterised by the fact that said grip (21) has a series of guide holes for drilling bits, alignable with the holes (7, 8, 15) of the cephalic and diaphysis screws in the drilling phase of the bone. 5

16. Intramedullary cavity nail according to claim 14, characterised by the fact that said instrument comprises a special tool (29) with a longitudinal stem (30) having a head (31) with central locking means (32) and with lateral gripping means (33) of the head of the screw for avoiding accidentally dropping it. 10

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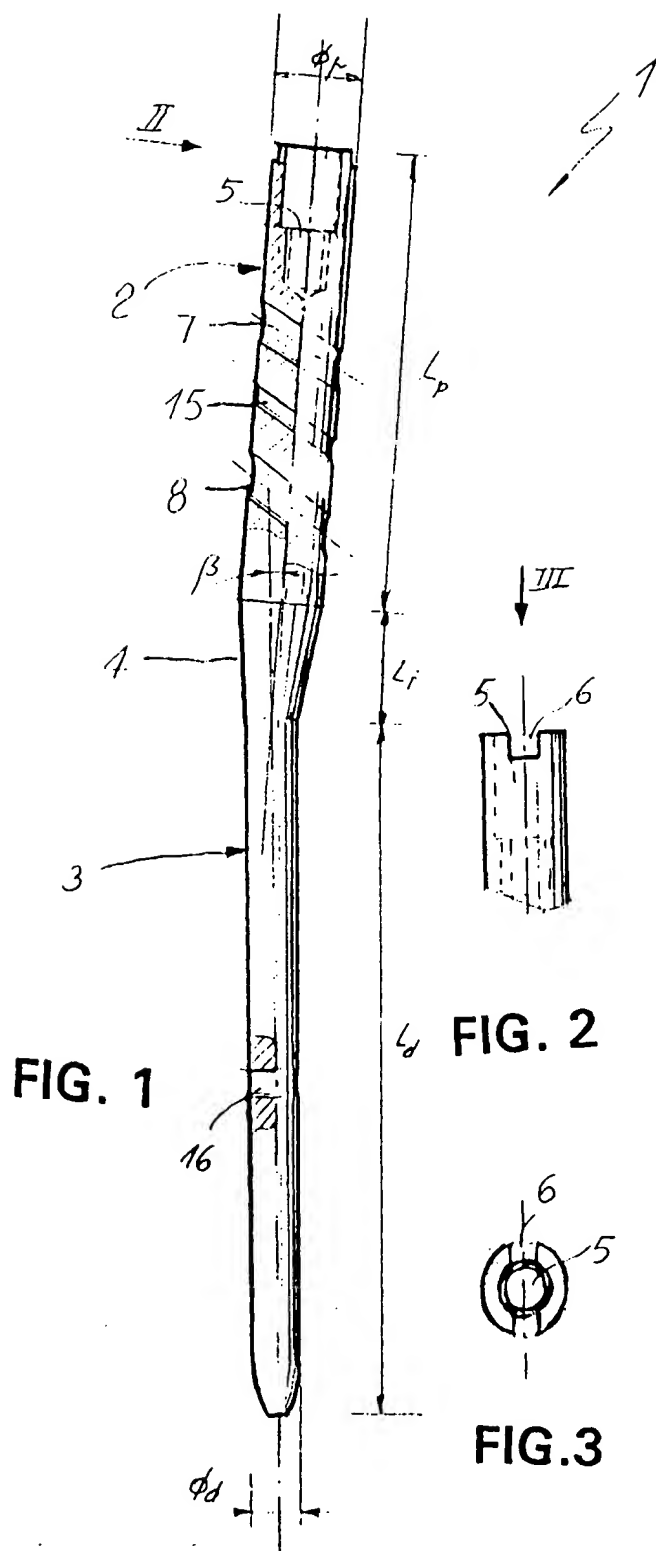
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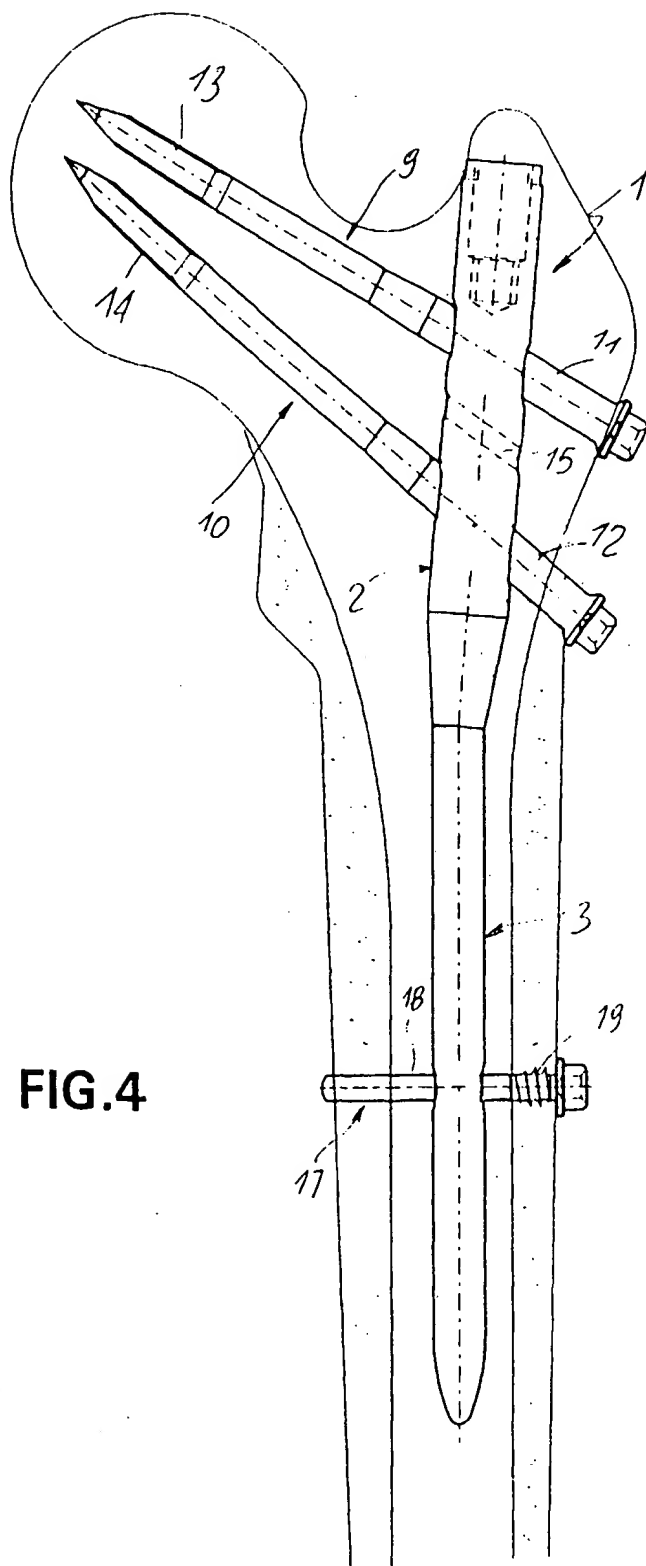


FIG.4

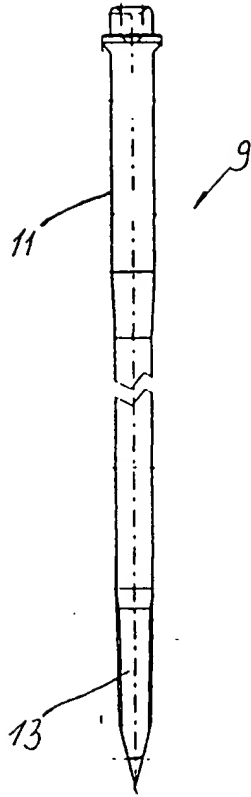


FIG. 5

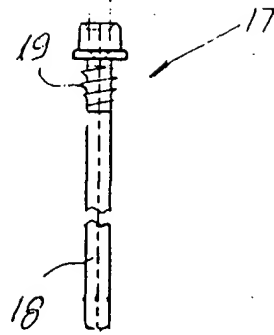


FIG. 6

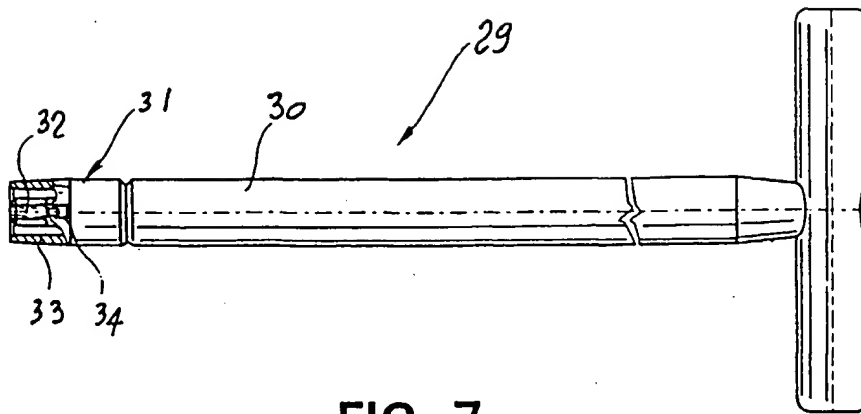


FIG. 7

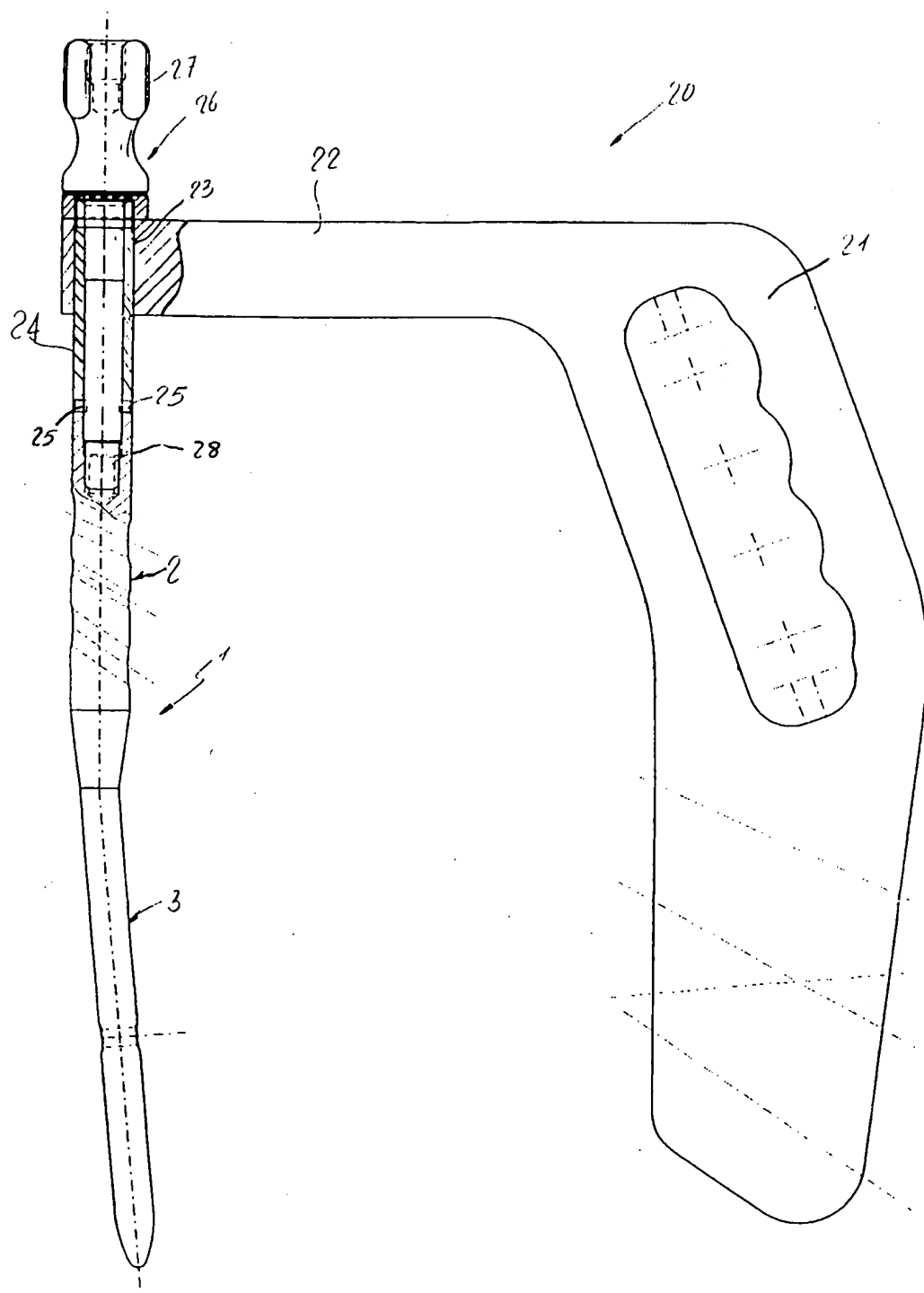


FIG. 8



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## EUROPEAN SEARCH REPORT

Application Number  
EP 97 12 2921

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	EP 0 736 286 A (ENDOCARE AG) * column 6, line 20 - line 28 * * column 8, line 33 - line 46; figures 2,8 *	1-4,9, 12-15	A61B17/74 A61B17/17
X	US 5 573 536 A (GROSSE ARSENE ET AL) * claims 1-3 *	1-3,9, 12,13	
X	US 5 429 640 A (SHULER THOMAS E ET AL) * column 16, line 16 - line 27; figures 12-19 *	1,4-7,9, 12,13	
X	US 4 875 474 A (BORDER ROBERT) * column 3, line 66 - column 4, line 7 * * column 4, line 35 - line 66; figures 1-4 *	1,4,5,9, 12,13	
X	US 5 562 666 A (BRUMFIELD DAVID L) * column 5, line 56 - column 6, line 4; figures 11,12 *	1,2,6,9	TECHNICAL FIELDS SEARCHED (Int.Cl.6) A61B
A	US 4 622 959 A (MARCUS RANDALL E) * column 5, line 17 - line 31 * * column 8, line 26 - line 29; figures 1,3 *	1,6,7	
A	EP 0 640 318 A (SYNOS MEDICAL SPA) * abstract; figures 1-5 *	1-3, 6-10, 12-16	
A	EP 0 355 411 A (ACE ORTHOPEDIC MFG) * column 8, line 28 - line 40 * * column 9, line 15 - line 20; figure 2 *	1-5,8	
The present search report has been drawn up for all claims			
Place of search BERLIN		Date of completion of the search 9 April 1998	Examiner Hansen, S
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

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# EUROPEAN SEARCH REPORT

Application Number  
EP 97 12 2921

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
A	FR 2 713 914 A (MEDINOV SA ;CATON JACQUES; TROUILLOUD PIERRE) * figure 4 * -----	1,2,9,10	
			TECHNICAL FIELDS SEARCHED (Int.Cl.6)
The present search report has been drawn up for all claims			
Place of search BERLIN		Date of completion of the search 9 April 1998	Examiner Hansen, S
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